

XYLOMETAZOLONI HYDROCHLORIDUM 5 g

Lot No.: 24I09-F240116

Authorisation:	1890R05441	Date Of Analysis:	04/10/2024
Analytical Reference:	Ph.Eur. [01/2008:1162]	Production Number:	160924-G240151
CNK:	3491-008	Expiry Date:	03/2029

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white, crystalline powder	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification A	The spectrum complies with the spectrum obtained with xylometazoline hydrochloride CRS	Complies
Identification E	Reaction of (a) chlorides	Complies
TESTS	SPECIFICATION	RESULT
Appearance of solution	Complies	Complies
Acidity or alkalinity	Complies	Complies
Related substances		
Impurity A	≤ 0.2%	0.002%
Unspecified impurities	≤ 0.10%	< 0.05%
Total	≤ 0.5%	< 0.05%
Loss on drying	≤ 0.5%	0.04%
Sulfated ash	≤ 0.1%	0.04%
ASSAY	SPECIFICATION	RESULT
Potentiometric titration	99.0% to 101.0% (dried substance)	99.9%
Manufacturer identification code: S/GS/009		

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: